

REMARKS

Claims 1-17, 19-22, 25-65, 69-80 and 82-115 are pending in the current application. Claims 18, 23-24, 66-68 and 81 have been cancelled. Claims 1-2, 4, 6, 8, 11-13, 16-17, 19-22, 25-44, 46-47, 49, 51-52, 62, 71, 87 and 89 have been amended. Claim 92-115 have been added. Support for the amendments and new claims may be found throughout the specification, including in the originally filed claims. For example, claims 16-17, 19-22, 25-44 have been amended to comprise at least one Neisserial autotransporter and to incorporate antigens supported by the originally filed multiple dependent claims. No new matter is added.

ELECTION/RESTRICTION

A requirement for restriction has been made under 37 C.F.R. 1.499 between the inventions of:

- I. Claims 1-60, 61 and 82-91, drawn to an immunogenic composition comprising antigens.
- II. Claim 62, drawn to a vaccine comprising polynucleotides.
- III. Claims 63-68, 80-81, drawn to a method of treatment or prevention.
- IV. Claims 69-76, drawn to a method of making an immunogenic composition.
- V. Claims 77-79, drawn to a method of preparing an immune globulin.

Applicants elect Group I without traverse to expedite prosecution. However, Applicants note that the Examiner alleges that the inventions of Groups I-IV lack the same or corresponding special technical features. The Office Action states that

[t]he claimed inventions are drawn to an immunogenic composition and vaccines for the treatment of Neisserial disease. The claimed immunogenic composition comprising two or more different antigens selected from a) at least one Neisserial adhesin; b) at least one Neisserial autotransporter; at least one Neisserial toxin; at least one Neisserial Fe acquisition protein; or at least one Neisserial membrane associated protein, preferably integral outer membrane protein.

(page 2, Office Action). Furthermore, the Examiner states that “[t]he technical feature of groups I and IV are not special in view of the teachings of Robinson et al (WO/00/25811, filed in the IDS). Robinson et al disclose a multicomponent

meningococcal vaccine comprising transferring binding proteins A and B (TbpA and TbpB) with other components such as Neisserial outer membrane vesicles and Cu,Zn-superoxide dismutase.” (*id.*) However, Robinson *et al.* do not disclose an immunogenic composition as claimed by Applicants, comprising at least one autotransporter antigen and at least one different protein antigen selected from a) at least one Neisserial adhesin; b) at least one Neisserial toxin; c) at least one Neisserial Fe acquisition protein; or d) at least one Neisserial membrane associated protein. Instead, Robinson *et al.* relates to compositions containing transferrin binding proteins, alone, or in combination with *N. meningitidis* outer membrane vesicles, or in combination with one or more liposomes, or in combination with one or more liposomes with Neisserial surface protein A. Therefore, Applicants respectfully submit that Robinson *et al.* do not disclose compositions that include a Neisserial autotransporter and one or more different antigens and do not disclose the special technical feature shared by the amended claims of Group I-IV. Nonetheless, as stated above, Applicants elect the subject matter of Group I (claims 1-60, 61, 82-91) without traverse.

Election of Species:

The Office Action, in paragraph 3, also requires election of species of the generic invention. Applicants elect the following species for purposes of initial examination on the merits.

3. 1) From among Neisserial adhesin species: A) FhaB, B) NspA, C) PilC, D) Hsf, E) Hap, F) MafA, G) MafB, H) Omp26, I) NMBO315, J) NMB0995, K) NMB 1119 and L) NadA, **Applicants elect Neisserial adhesin species (B) NspA.**

3.2) From among the following Neisserial autotransporter species: A) Hsf, B) Hap, C) IgA protease, D) AspA and E) NadA, **Applicants elect Neisserial autotransporter species (A) Hsf.**

3.3) From among Neisserial toxin species: A) FrpA, B) FrpC, C) FrpA/C, D) VapD, E) NM-ADPRT, F) LPS immunotype L2 and G) LPS immunotype L3, **Applicants elect Neisserial toxin species (C) FrpA/C.**

3.4) From among Neisserial Fe acquisition species: A) TbpA high, B) TbpA low, C) TbpB high, D) TbpB low, E) LbpA, F) LbpB, G) P2086, H) HpuA, I) HpuB,

J) Lipo28, K) Sibp, L) FbpA, M) BfrA, N) BrfB, O) Bcp, P) NMB0964, and Q) NMB0293, **Applicants elect Neisserial Fe acquisition species (A) TbpA high.**

3.5) From among Neisserial membrane associated protein species: A) PilQ, B) OMP85, C) FhaC, D) NspA, E) TbpA(high), F) TbpA(low), G) LbpA, H) HpuB, I) TspA, J) TspB, K) TdfH, L) PorB, M) HimD, N) HisD, O) GNA1870, P) OstA, Q) HlpA, R) MltA, S) NMB 1124, T) NMB 1162, U) NMB 1220, V) NMB 1313, W) NMB 1953, X) HtrA, and Y) PldA, **Applicants elect Neisserial membrane associated protein species (B) OMP85.**

3.6) From among genes to down regulate species: A) lgtB, B) lgtE, C) siaD, D) ctrA, E) ctrB, F) ctrC, G) ctrD, H) synA, I) synX, J) siaA, K) synB, L) siaB, M) synC, N) siaC, O) OpC, P) OpA, Q) PorA, R) frpB, S) msbB, and T) htrB, **Applicants elect genes to down regulate species (A) lgtB.**

3.7) From among antigen derived from: (and Infection is:) species: A) *Neisseria meningitidis* and B) *Neisseria gonorrhoeae*, **Applicants elect species (A) *Neisseria meningitidis*.**

3.8) From among bacterial capsular polysaccharide/oligosaccharide derived from: species: A) *Neisseria meningitidis*, B) *Haemophilus influenzae* b, C) *Streptococcus pneumoniae*, D) Group A *Streptococci*, E) Group B *Streptococci*, F) *Staphylococcus aureus* and G) *Staphylococcus epidermidis*, **Applicants elect species (A) *Neisseria meningitidis*.**

Applicants are also required to further elect a single species of *N. meningitidis* serotype from which the capsular polysaccharide is selected from A) serogroup A, B) serogroup B, C) serogroup C, D) serogroup Y, and E) serogroup W-135. Applicants provisionally elect *N. meningitidis* serotype species (C) serogroup C. Applicants note that claim 52 does not stipulate the presence of polysaccharide or oligosaccharide, and thus cannot be subject to this election of species. Applicants believe that the Examiner meant to require this election with reference to claims 55 and 56, which include the limitation of one or more bacterial capsular polysaccharides or oligosaccharides. Accordingly, for the purpose of initial examination, Applicants elect compositions, further comprising one or more bacterial capsular polysaccharides or oligosaccharides from *Neisseria meningitidis* serogroup C.

Claims 1-11, 13-15, 17, 20, 22, 45, 50-52, 54-64, 69-80, 82-83, 85-88, 90, 93, 95-96, 98, 103, and 114-115 read on the elected species.

In the event that one or more generic claims are found to be allowable, Applicants respectfully request examination of additional species which are dependent from or otherwise include all the limitations of the allowable generic claims as required under 37 C.F.R. 1.141.

Applicants also note that the subject matter of Groups I, III, and IV are related to each other as product, a process of using the product, and a process for making the product, respectively. When product claims (for example, one or more of Claims 1-60, 61, and/or 82-91) are found to be allowable, Applicants respectfully request rejoinder of process claims that are dependent or otherwise include all the limitations of the allowed product claims as required by MPEP § 821.04(b).

Applicants expressly reserve the right to prosecute the subject matter in the non-elected claims, originally filed claims, or any other claims supported by the specification in one or more continuing applications.

CONCLUSION

Applicants elect Group I without traverse (Claims 1-60, 61 and 82-91) and further elect the following species: Neisserial adhesin species (B) NspA, Neisserial autotransporter species (A) Hsf, Neisserial toxin species (C) FrpA/C, Neisserial Fe acquisition species (A) TbpA high, Neisserial membrane associated protein species (B) OMP85, genes to down regulate species (A) ItgB, antigen derived from: (and Infection is:) species (A) Neisseria meningitidis, bacterial capsular polysaccharide/oligosaccharide derived from: species (A) Neisseria meningitidis, and N. meningitidis serotype species (C) serogroup C.

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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